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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,176	04/23/2001	Ron Yacov	13257-00040	2969

22249 7590 05/16/2002

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/16/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,176

Applicant(s)

YACOV ET AL.

Examiner

Joseph Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

This application filed April 23, 2001, is a 371 National stage filing of PCT/US99/25477, filed October 29, 1999, which claims benefit of provisional application 60/106,533, filed October 31, 1998.

Claims 1-19 are pending and currently under examination.

Election/Restriction

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-3, 7 and 8, drawn to a composition comprising transduced myeloid committed stem cells and use of said cells for expressing exogenous nucleic acids in myeloid-committed stem cells *in vitro*.
- II. Claims 4-6, drawn to a vector suitable for treating Gauchers disease.
- III. Claims 9-14, drawn to a method of expressing exogenous nucleic acids in myeloid-committed stem cells in a subject wherein the myeloid-committed stem cells are introduced into a subject for treatment of Tay Sachs disease, Niemann-

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Pick disease, Gauchers disease, Hunters Syndrome and metachromatic leukodystrophy.

- IV. Claims 15-19, drawn to a method of potentiating an immune response to an antigen in a subject.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2 they lack the same or corresponding special technical features for the following reasons:

A) The inventions of groups I and II have been found by the Examiner to have no special technical feature that defined the contribution over the prior art. In the instant case, a myeloid cell is a cell 'pertaining to, derived from, or manifesting certain features of the bone marrow' (see definition of myeloid in Stedman's Medical Dictionary). Compositions comprising bone marrow and transduced bone marrow samples were previously taught in the art. Further, the sequences encoding glucocerebrosidase, hexaminidase A, iduronate-2-sulphatase, sphingomyelinase and arylsulfatase A, contained in a vector were previously taught in the art. The methods set forth in groups III and IV use myeloid cells, however because the cells and sequences were previously known in the art, it is found that there is no special technical feature which is defined over the prior art which links the different inventions.

B) Unity of invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

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- A) A product and a special process of manufacture of said product.
- B) A product and a process of use of said product.
- C) A product, a special process of manufacture of said product, and a process of use of said product.
- D) A process and an apparatus specially designed to carry out said process.
- E) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850.

In the instant case a composition of myeloid cells can be used in bone marrow transfusions, and transduced cells could be used to produce a protein *in vitro* or to study the affect of the expression of a particular protein on the growth and/or differentiation of said cell composition. The instantly claimed vectors can be used to transduce other cell types or as probes for the detection of the particular sequence contained in said vector. It is noted that unity of invention between different categories of inventions can be found to exist if specific combinations of inventions are present. In the instant case the product of group I and the first process of use set forth for using said product, as drawn to a method of expressing a protein *in vitro* in claims 7 and 8, have been found to have unity of invention PCT Rule 13.1-13.2. The methods set forth in groups III and IV represent additional potential uses for myeloid cells.

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Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention.

Because these inventions are distinct for the reasons given above have acquired a separate status in the art as shown by their divergent subject matter restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Voitach

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AU1632